UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,237	06/05/2006	Karin Golz-Berner	101215-228	3867

27387 7590 05/11/2010

LONDA, BRUCE S.
NORRIS MCLAUGHLIN & MARCUS, PA
875 THIRD AVE, 8TH FLOOR
NEW YORK, NY 10022

EXAMINER	
BUCKLEY, AUDREA	
ART UNIT	**PAPER NUMBER**
1611	

MAIL DATE	DELIVERY MODE
05/11/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,237	GOLZ-BERNER ET AL.	
	Examiner	Art Unit	
	AUDREA J. BUCKLEY	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-24,26,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-24,26,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/17/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Acknowledgement is made of Applicant's claim amendments and remarks/arguments filed 2/10/2010.

Claims 17-24, 26, 30, and 31 are pending and under consideration herein.

Withdrawn Claim Rejections

The rejection of claims 17, 18, 20, 23, 24, 26, and 31 under 35 U.S.C. 102(b) as being anticipated by Stora as evidenced by Critical Care Medicine Tutorials is withdrawn in light of Applicants' amendments to the claims filed 2/10/2010.

The rejection of claim 30 under 35 U.S.C. 103(a) as being unpatentable over Stora is withdrawn in light of Applicants' amendments to the claims filed 2/10/2010.

The rejection of claim 18 under 35 U.S.C. 103(a) as being unpatentable over Stora in view of Gross et al. is withdrawn in light of Applicants' amendments to the claims filed 2/10/2010.

The rejection of claims 21, 22, 25, and 27 under 35 U.S.C. 103(a) as being unpatentable over Stora in view of Gross et al. is withdrawn in light of Applicants' amendments to the claims filed 2/10/2010.

The rejection of claim 19 under 35 U.S.C. 103(a) as being unpatentable over Stora in view of Gross et al. and Pelle et al. is withdrawn in light of Applicants' amendments to the claims filed 2/10/2010.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is vague and indefinite because the metes and bounds of the term "wherein the carrier system is loading with an oxygen content of 25-40% oxygen content by volume of the initial oxygen content..." are unclear. The phrase is unclear in that it can be interpreted in two different ways: (i) requiring an additional step where, at post-loading, the carrier system is again loaded with additional oxygen, or (ii) as a functional limitation where, at four weeks post-loading, the carrier composition comprises between 25-40% of the initial oxygen content by volume. It would be remedial to amend the claim to clearly distinguish between these two distinct interpretations of the instant claim language.

It is noted that Applicants did not specifically address the rejection of claim 18 under 35 U.S.C. 112, second paragraph. The rejection is maintained for the reasons already made of record as the claim language remains vague and indefinite.

New Grounds of Rejection as Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 20, 23, 24, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109, patented Jun. 2002) as evidenced by Critical Care Medicine Tutorials (web archive 2002, accessed 11/9/2009).

Regarding claims 17, 20, 23, and 24, Stora teaches perfume compositions free of organic solvents, existing in emulsified form, and capable of delivering the active agent to the skin (see abstract, in particular). Example 1 teaches a formulation comprising 2.23% perfluorodecaline, a fluorinated hydrocarbon; 24.95% Silicone DC®345, a silicone polymer; and 10.05% of a perfuming oil base; the perfluorodecaline is the oxygen carrier system as in instant claims 1 and 24. Further, the instantly claimed partial pressure of gaseous oxygen is an inherent property since the atmospheric partial pressure of oxygen necessarily lies within the instantly claimed range. As stated in the Critical Care Medicine Tutorials, oxygen, being a gas, exerts a partial pressure, which is determined by the prevailing environmental pressure and, at sea level, is 159 mmHg, a value which falls within the instantly claimed range of up to 250-400 mbar. As to claim 30, Examples 3 and 4 teach a presence of 55.12% by weight of Silicone DC®345 (a silicone polymer). As to claim 31, Stora teaches topically applicable emulsions with controlled refractive indices and viscosity values. Therefore, these emulsions are formed as topically applicable lotions, creams, or gels (see column 2, lines 3-48).

Regarding claim 17, the embodiments of the invention of Stora do not illustrate a formulation having an oxygen carrier system having a presence between 6 and 10% by mass of the total formulation. For this reason, this rejection is made using obviousness rationale. However, it would have been within the skill of the artisan to dilute the base formulation presented above prior to application in order to optimize the formulation's efficacy.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to adjust the formulation components in order to optimize the properties of the product. The skilled artisan would have been motivated to do so, in accordance with the teachings of Stora plus the ordinary skill of the artisan, in order to maximize the effects of the delivered formulation and to minimize cost and potential negative effects of application, as is routine in the art. The oil-in-water emulsion system of Stora utilizes this oil-and-water carrier in order to deliver an active agent. The emulsion balance facilitates the dissolution of the active agent while maintaining desirable application properties (devoid of organic solvents, desirable refractive index properties/ transparency). For instance, upon subtraction of the perfume component (up to approximately 10% of the total formulation), the remaining components would have been present in a greater percentage (than the embodiments presented by Stora). It would have been obvious to the skilled artisan to perform optimization (i.e., remove or decrease a component presence, such as perfume) procedures in order to control the properties (i.e., smell, strength of smell, oily feel, emulsion stability, etc.) of the overall formulation and to impart the desired active agent for the desired intended use of the product.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) as evidenced by Critical Care Medicine Tutorials (web archive 2002, accessed 11/9/2009) as applied to claims 17, 20, 23, 24, 30, and 31,

and further in view of Gross et al. (US 5,637,318, (hereinafter, the '318 reference), patented Jun. 1997).

The teachings of Stora are delineated above. As to claim 18, the functional limitation of oxygen content inherently would lie within the range of 25-40% upon loading according to the instant specification. For example, page 2 of the instant specification (paragraph 5) describes the oxygen loading in which oxygen gas within a broad range of partial pressures is bubbled through the carrier system with stirring at ambient temperature for a specified time period. Upon bubbling oxygen through the carrier composition as described, the oxygen presence necessarily would result in an oxygen quantity equal to or approximating the quantity instantly claimed. Upon the interpretation of claim 18 that an additional step is required (see maintained rejection under 35 USC 112), it is noted that the loading of an oxygen content is a product-by-process limitation, which lacks patentable weight in accordance with MPEP 2113. Even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, if the product in the product by process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Stora do not teach a quantitative value for oxygen loading in a perfluorinated hydrocarbon carrier as in the instant claim.

Gross et al. ('318) teach oxygen-laden fluorocarbons and fluorocarbon mixtures suitable for dermatological use (see abstract, in particular). Additionally, Gross et al. state that fluorocarbons are capable of transporting oxygen (see '318 reference, column 2, line 39) and with the aid of known oxygen gas solubilities, the vapor pressure (an inherent property), and the critical solubility temperature, the loading of fluorocarbons with oxygen can be adjusted by the skilled artisan (see '318 reference, column 4, lines 21-26).

Therefore, regarding claim 18, it would have been prima facie obvious to one of ordinary skill in the art to adjust the presence of oxygen in a fluorocarbon carrier for a dermatological application as suggested by Gross et al. in order to improve the oxygen carrying capacity of a topically applicable composition such as the one taught by Stora. One would have been motivated to do so in order to optimize the benefits associated with oxygen delivery to the skin as evaluated according to the final product. Since this optimization process would have been routine procedure, the skilled artisan would have expected resulting success.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) as evidenced by Critical Care Medicine Tutorials (web archive 2002, accessed 11/9/2009) as applied to claims 17, 20, 23, 24, 30, and 31, and further in view of Gross et al. (US 5,643,601, (hereinafter, the '601 reference), patented Jul. 1997).

As to claim 22, Stora teach that the perfuming ingredients can belong to a variety of chemical classes including alcohols, esters, acetates, terpenic hydrocarbons, and essential oils of natural or synthetic origin (see column 5, lines 54-60).

Regarding claim 21, Stora does not expressly include a gelling or thickening agent in the carrier system. As to claim 22, Stora does not limit the carrier system oil base to one which is a vegetable oil, an ester, or a mixture thereof.

However, Gross et al. ('601) teach phospholipid-and fluorocarbon containing cosmetics to be formulated as gels, creams, lotions, etc. in order to supply adequate oxygen to the skin upon application (see abstract, in particular). Gross et al. teach that the fluorocarbons in this composition analogous to that of Stora can be selected for oxygen gas solubility, partial vapor pressure, and lipid solubility according to the specific intended application ('601 reference, see column 3, lines 28-30).

Gross names perfluorodecalin as a rapid release oxygen carrier which also is embodied in the invention (see '601 reference, column 3, line 34; see also, column 4, Table 1). Specifically, Gross teaches an embodiment in which the formulation had reached the dermal skin section at which the oxygen partial pressure rose to a value of 159 mmHg after a penetration period. As to claim 21, Gross et al. teach the inclusion of hydroxyethyl cellulose (a thickening agent), in a gel mask formulation of the invention (see '601 reference, column 7, example 9). As to claim 22, Gross et al. teach jojoba oil and liquid paraffin as components in Example 5, a body lotion. The skilled artisan would have recognized that jojoba oil is a liquid wax produced in the seed of the jojoba plant and is a mixture of wax esters desirably present in cosmetic and topical applications.

It would have been prima facie obvious to the skilled artisan to combine the teachings of Stora and Gross et al. in order to maintain the benefits of the fluorocarbon formulation component (i.e., optimized oxygen incorporation and delivery) and to further optimize this oxygen carrier component in the analogous product resulting from this combination of teachings. The skilled artisan would have been motivated to optimize physical properties such as formulation thickness and therefore manageability by including a known gelling agent such as hydroxyethyl cellulose as is routine in the cosmetic arts and as is suggested in the disclosure of Gross et al., particularly since Gross et al. state a variety of cosmetically acceptable formulations such as gels, pastes, ointments, creams, lotions, etc (see '601 reference, column 4, lines 10-11). Similarly, the skilled artisan would have been motivated to implement jojoba oil into the topically applicable formulations on account of its commonly recognized and desirable properties such as being odorless and relatively shelf-stable when compared with other vegetable oils useful as cosmetic carriers, as taught by Gross et al.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) as evidenced by Critical Care Medicine Tutorials (web archive 2002, accessed 11/9/2009) in view of Gross et al. (US 5,643,601) as applied above and further in view of Pelle et al. (US 5, 811,083, patented Sep. 1998), and Nakanishi et al. (S 6,576,623 B1, patented Jun. 2003).

The teachings of Stora and Gross are delineated above. Stora does not disclose the inclusion of tocopherol or a tocopherol derivative in the instantly prescribed quantity.

It is noted that Gross et al. teach the inclusion of antioxidants such as a- tocopherol (see '601 reference, column 3, lines 66-67) in analogous perfluorodecalin-containing cosmetic compositions.

However, neither of these references teach the instantly specified tocopherol derivatives in the instantly specified quantity.

However, Nakanishi et al. teach silicone compounds useful in cosmetic applications wherein tocopheryl succinate is taught as a functional equivalent to a-tocopherol (see column 10, lines 58-60).

Nonetheless, Pelle et al. specifically teach tocopherol derivatives for use in cosmetic compositions. Specifically, Pelle et al. disclose advantages of using tocopherol derivatives for regulating skin aging and other disorders and suggest a most preferred quantity of 0.01 to 1.0 wt. % for topical applications (see column 7, lines 32-36). Further, the skilled artisan would have been motivated to optimize this formulation component presence in order to impart desired properties to the final product. MPEP 2144.05 addresses the patentability of routine optimization procedures as quoted above.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute tocopheryl succinate as taught by Nakanishi for the a-tocopherol disclosed in the formulations of Gross et al. One would have been motivated to do so since these a-tocopherol and tocopheryl succinate have been shown in the prior art to be interchangeable and to have insubstantial differences both structurally and functionally.

Likewise, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Pelle et al. with the teachings of Gross et al. in order to determine a desirable quantity of tocopherol derivative in a cosmetic formulation. Also, it would have been prima facie obvious to combine the teachings of Gross et al. and Stora and to utilize Gross' suggestion to include tocopherol or its derivative in a topically applicable perfluorodecalin-containing cosmetic composition. One would have been motivated to combine these teachings since Gross et al. teaches the advantage of avoiding auto-oxidation processes in other formulation components by adding an anti-oxidant such as alpha-tocopherol to a formulation analogous to that of Stora. Since Gross et al. does not specify an acceptable quantity, the skilled artisan would have been motivated to look to Pelle et al. in order to determine a topically acceptable quantity of the tocopherol agent.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) as evidenced by Critical Care Medicine Tutorials (web archive 2002, accessed 11/9/2009) as applied to claims as applied to claims 17, 20, 23, 24, 30, and 31 above and further in view of Lu (US 2003/0235548 A1, filed Jun. 2002).

The teachings of Stora are delineated above. As to claim 26, Stora does not teach an embodiment of the invention in which a silicone oil is present in a quantity between 6 and 35% by mass of the total formulation.

However, Lu teaches cosmetic formulations structured with silicone polymers wherein the formulations include a liquid fatty phase comprising at least one silicone oil. Specifically, the liquid fatty phase advantageously contains at least 30% by weight of silicone oil(s).

Although Lu does not teach the exact limitation as in the instant claim, Lu teaches a premise from which the skilled artisan would have been inclined to optimize. Lu teaches a range of silicone oil overlapping with the range instantly claimed. See MPEP 2144.05 regarding the patentability of overlapping ranges.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to implement the quantity of silicone oil as taught by Lu in the formulations of Stora. One would have been motivated to do so since Lu teaches that the silicone polymers used in the invention are more soluble in low-viscosity silicone oils (see page 5, paragraph [0074]).

Response to Arguments

Applicant's arguments presented 2/10/2010 have been fully considered but are moot in light of amendment and are otherwise unpersuasive. As noted above, all rejections previously presented and not re-iterated herein are withdrawn. Applicant's positions against cited references are summarized and responded to as follows.

Applicants state that amended claim 17 requires partial pressure of the oxygen loading to be in the range of 250-400 mbar. Applicants take the position that there is no motivation to provide a range of perfluorinated hydrocarbon supporting the gaseous

oxygen at an elevated level. In response, it is noted that the claim language reads as follows "…with gaseous oxygen up to a partial pressure of 250-400 mbar O2". The claim language "up to" has been interpreted to mean that the range of 250-400 mbar is a maximum range, such that any value up to one of these quantities is included. As such, the relevance of the Stora reference as evidenced by Critical Care Medicine Tutorial is maintained as newly applied in the obviousness rejection above.

Applicants present that phospholipids as oxygen carriers have been addressed in the specification. Applicants further submit a Declaration presenting data from which Applicants conclude that the presence of silicone polymer acts synergistically with the perfluorinated hydrocarbon to significantly increase oxygen retention over time. In reply, Applicants' position has been fully considered but is not persuasive since the structural claim limitations have been met by the cited prior art as applied above.

Applicants point out that the amended claim 19 is now limited to specific tocopherol derivatives. Applicants mention that the purpose of adding tocopherol derivative(s) to the claimed system is not for anti-oxidative effect but rather to improve the stability of the formulations; Applicants take the position that there is no suggestion in Pella to add the tocopherol derivatives to the compositions of Stora. The relevance of these references is maintained as newly articulated above.

Conclusion

No claims are found allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA J. BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611